UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE MEDICINES COMPANY,	:	
	:	Index No. 13 MISC 0011 (WHP)
Plaintiff,	:	
	:	
v.	:	
	:	(Related Case No. 1:11-CV-01285,
MYLAN INC., MYLAN	:	U.S. District Court for the Northern
PHARMACEUTICALS INC., and	:	District of Illinois)
BIONICHE PHARMA USA, LLC,	:	
	:	
Defendants.	:	

NONPARTY FROMMER LAWRENCE & HAUG LLP'S MEMORANDUM IN OPPOSITION TO MYLAN INC.'S, MYLAN PHARMACEUTICALS INC.'S, AND BIONICHE PHARMA USA, LLC'S MOTION TO COMPEL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

I. PRELIMINARY STATEMENT

The present discovery dispute stems from a patent-infringement case between: (i) plaintiff The Medicines Company; and (ii) defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively "Mylan"). In 2011, The Medicines Company sued Mylan for infringement of two pharmaceutical patents in the Northern District of Illinois, Civil Action No. 1:11-CV-01285 (N.D. Ill.). The discovery that Mylan currently seeks in its motion to compel purportedly relates to its inequitable-conduct defense, which alleges that the two co-inventors of the pharmaceutical patents committed inequitable conduct before the United States Patent and Trademark Office ("Patent Office"). Mylan's motion largely rests on a purported waiver of the attorney-client privilege that allegedly occurred during Dr. Kuzmich's January 3, 2013 deposition.

Mylan's motion seeks: (i) privileged documents related to Lot No. 134498; (ii) privileged documents between Frommer Lawrence & Haug LLP ("FLH") and Dr. Motheram; (iii) a second deposition of Dr. Kuzmich; and (iv) an order requiring FLH to collect, produce, and log documents responsive to Mylan's subpoena, including "three spreadsheets" discussed by Dr. Kuzmich during her deposition.

As discussed in detail below, Mylan's motion to compel should be denied. There can be no waiver of the attorney-client privilege if there was no privileged communication in the first instance. Dr. Motheram did not provide information to Dr. Kuzmich for the purpose of seeking or obtaining legal advice. Accordingly, no privileged communication between Drs. Motheram and Kuzmich ever existed. And even if Dr. Motheram did provide information to Dr. Kuzmich for the purpose of seeking or obtaining legal advice—an assertion by Mylan that is unsupported by the record—no waiver occurred because the attorney-client privilege does not attach to underlying facts or information. Dr. Kuzmich's discussion of facts learned through her

communication with Dr. Motheram cannot give rise to a waiver.

In addition to denying Mylan's motion to compel the production of privileged documents, the Court should also deny its request for a second deposition of Dr. Kuzmich. There is no justification for a second deposition of Dr. Kuzmich because she has already provided the full extent of her knowledge of her communication with Dr. Motheram. (*Infra* Sec. III.D.) Finally, there are no logged privileged documents that related to Lot No. 134498. FLH has already collected, produced, and logged documents responsive to Mylan's subpoena, including producing copies of the three requested spreadsheets. Mylan's motion to compel is without merit and should be denied.

II. BACKGROUND

A. Mylan's Inequitable-Conduct Allegations Against Inventors Drs. Musso and Krishna and The Medicines Company's Patents

Drs. Musso and Krishna discovered, among other things, a novel bivalirudin drug product with minimized levels of the Asp^9-bivalirudin impurity and a novel way to make the bivalirudin drug product with minimized levels of the Asp^9-bivalirudin impurity. Generally, the two pharmaceutical patents claim: (i) pharmaceutical batches of bivalirudin drug product with low levels of the Asp^9 impurity; or (ii) a product made by a defined process for making bivalirudin drug product with low levels of the Asp^9 impurity. For example, the patents claim pharmaceutical batches of bivalirudin with maximum Asp^9-bivalirudin impurity levels that do not exceed "about 0.6%."

One particular lot of bivalirudin manufactured by The Medicines Company's contract manufacture Ben Venue Laboratories ("Ben Venue")—Lot No. 1344985—had a high Asp^9-bivalirudin impurity level. Mylan asserts that Drs. Musso and Krishna—who are not mentioned in Mylan's motion—committed inequitable conduct because they did not disclose Lot No.

1344985 to the Patent Office during the prosecution of the bivalirudin patents. For reasons that are not relevant to Mylan's motion to compel, the co-inventors did not commit inequitable conduct, including with respect to Lot No. 1344985. This lot was not material to patentability and the inventors did not have the requisite intent to deceive the Patent Office.

B. Mylan's Subpoena and FLH's Document Productions

On December 2012, Mylan served a document subpoena on FLH. In response, FLH agreed to produce nonprivileged documents. FLH's December 28th and January 2nd productions contained over a thousand pages. On January 11th, FLH produced additional documents and a supplemental privilege log. The additional documents produced by FLH on January 11th contain the "three spreadsheets" and the existing transmittal documents that Mylan currently seeks. The supplemental FLH privilege log lists 75 entries. (Fleming Ex. 1.)[1]

C. Dr. Kuzmich's Statements Made During Her Deposition Relating to Lot No. 1344985

Mylan deposed Dr. Kuzmich on January 3, 2013 in both her personal capacity and as a Rule 30(b)(6) witness for The Medicines Company. Among other topics, Mylan questioned Dr. Kuzmich about Lot. No. 1344985 and her conversation with Dr. Motheram concerning that lot. During her deposition, Dr. Kuzmich provided facts related to her conversation with Dr. Motheram including that: (i) she had an "in person or via telephone" conversation with Dr. Motheram regarding Lot No. 1344985 (ECF No. 15-23, Kuzmich Dep. 192:23-193:4); (ii) she became aware of Lot No. 1344985 after The Medicines Company had paid the issue fee but before issuance of the two patents (*id*., Kuzmich Dep. 185:2-186:4); (iii) Dr. Motheram believed "there were issues surrounding Ben Venue procedures following manufacturing processes" (*id*., Kuzmich Dep. 198:23-25); (iv) the FDA had warned Ben Venue about manufacturing issues that

[1] "Fleming Ex. __" refers to the exhibits in the accompanying declaration of Porter F. Fleming.

may constitute violations of the Food Drug and Cosmetic Act (*id*., Kuzmich Dep. 197:11-16); and (v) in The Medicines Company's and Dr. Motheram's technical opinion, "the [new compounding] procedure was not followed for [Lot No. 1344985] . . . ." (*id*., Kuzmich Dep. 199:3-7).

III. ARGUMENT

A. The Court Should Deny Mylan's Motion to Compel Privileged Documents Because a Waiver Cannot Occur if a Privileged Communication Does Not Exist

There can be no waiver of the attorney-client privilege if there is no privileged communication. *See, e.g., American Standard Inc. v. Pfizer Inc.*, 828 F.2d 734, 746 (Fed. Cir. 1987); *In re Gaming Lottery Sec. Litig.*, No. 96 Civ. 5567, 2000 WL 1171166, at *6 (S.D.N.Y. Aug. 17, 2000). Mylan incorrectly asserts that Dr. Kuzmich waived the attorney-client privilege by testifying as to only factual information learned through a conversation with Dr. Motheram. (Mem. at 1-2.) Mylan's waiver argument fails because it incorrectly assumes that this conversation was made for the purpose of seeking or obtaining legal advice. Here, no privileged communication existed. Dr. Motheram only provided Dr. Kuzmich information concerning facts—an investigation associated with Lot No. 1344985 and manufacturing issues at Ben Venue.

When determining whether a communication constitutes a privileged communication, this Court applies Second Circuit law. *In re Pioneer Hi-Bred Intern., Inc*., 238 F.3d 1370, 1374 (Fed. Cir. 2001). The attorney-client privilege attaches:

> (1) where legal advice of any kind is sought (2) from a professional legal advisor in his capacity as such, (3) the communications relating to that purpose, (4) made in confidence (5) by the client, (6) are at his instance permanently protected (7) from disclosure by himself for by the legal advisor, (8) except the protection be waived.

In re Grand Jury Subpoena Duces Tecum Dated Sept. 15, 1983, 731 F.2d 1032, 1036 (2d Cir. 1984).

As demonstrated by Dr. Kuzmich's deposition testimony, Dr. Motheram did not seek legal advice and instead reported facts and his pre-existing technical opinion with respect to ongoing events involving investigations by the Food and Drug Administration ("FDA") into manufacturing conditions at Ben Venue as well as investigations by Ben Venue into Lot No. 1344985. Under such circumstances, "Courts have remained firm . . . in denying privileged status to documents that contain essentially technical or business data and are not primarily legal in nature." *See, e.g., Weil Ceramics & Glass, Inc. v. Work*, 110 F.R.D. 500, 504 (E.D.N.Y. 1986) (emphasis added). As shown by Dr. Kuzmich's testimony below, Dr. Motheram did not seek and Dr. Kuzmich did not give any legal advice of any kind:

> Q. [Dr. Motheram] just said there were some FDA 483 citations and issues surrounding Ben Venue manufacturing processes and procedures and so I don't think the new compounding process was followed and he just left it at that?
>
> . . .
>
> A. [Dr. Motheram's] statement was that there were issues surrounding Ben Venue procedures following manufacturing processes. There had been 483 FDA citations and that the view or the opinion at [T]he Medicines Company and in his view was that the procedure was not followed for [Lot No. 1344985], that batch. That is the information he gave us.

(ECF No. 15-23, Kuzmich Dep. 198:13-199:7) (emphasis added.) Contrary to Mylan's assertions, Dr. Motheram's transmittal of technical information to Dr. Kuzmich does not transform that communication into a request for legal advice. And because Dr. Motheram's statements do not give rise to a privileged communication in the first instance, Dr. Kuzmich could not subsequently waive privilege. *See, e.g., American Standard,* 828 F.2d at 746 (holding

that the district court properly determined that there was "no need to consider whether any waiver might have encompassed the particular testimony and documents sought by American Standard and claimed by Biomet as privileged" because "the opinion letter here at issue did not reveal confidential communications and therefore was not privileged . . . .").

In analyzing the issue of waiver under similar circumstances, the Southern District of New York has held that the attorney-client privilege does not protect "merely business-related or technical communications . . . ." *In re Rivastigmine Patent Litig. (MDL No. 1661)*, 237 F.R.D. 69, 80 (S.D.N.Y. 2006); *see also In re Application of Minebea Co., Ltd.*, 143 F.R.D. 494, 502 (S.D.N.Y. 1992). For example, in *Minebea*, the Court analyzed the waiver-of-privilege issue and noted that it is the "general rule that communications of 'technical information' between the client and the attorney for the purpose of submission to the PTO in the patent application are not privileged. This is not an absolute rule, however: where the primary purpose of the communication is securing or conveying legal advice, the privilege will be upheld despite the inclusion of technical data in the communication." *Minebea*, 143 F.R.D. at 502. Mylan, without support, seeks to contravene the general rule. Dr. Motheram provided his pre-existing technical opinion (including his opinion on Lot No. 1344985) to Dr. Kuzmich without any request for legal advice. (ECF No. 15-23, Kuzmich Dep. 198:13-199:7.)

Thus, Dr. Motheram's communication does not constitute a privileged communication. *See In re Rivastigmine Patent Litig.,* 237 F.R.D. 69 at 80; *Minebea*, 143 F.R.D. at 502. And because the technical factual information provided by Dr. Motheram to Dr. Kuzmich does not constitute privileged information, The Medicines Company is not using it as a "sword" while "shielding" privileged information (Mem. at 2). This Court should deny Mylan's motion to compel.

B. Even if the Attorney-Client Privilege Applied, The Medicines Company Did Not Waive Privilege by Disclosing Facts Related to the Investigation of Lot No. 1344985 and the FDA's Investigation of Ben Venue

Even if the Court determines that an attorney-client communication did exist, the Court should deny Mylan's motion because the attorney-client "privilege only protects disclosure of communications; it does not protect disclosure of the underlying facts by those who communicated with the attorney . . . ." *Upjohn Co. v. United States*, 449 U.S. 383, 395-96 (1981); *see also Minebea*, 143 F.R.D. at 501 (the privilege "attaches only to the communication between the attorney and the client, not to the underlying facts or information.") (citations omitted). Here, Dr. Kuzmich only disclosed the facts underlying her conversation with Dr. Motheram. Specifically, Dr. Kuzmich disclosed the following facts during her deposition:

- The fact that she had an "in person or via telephone" conversation with Dr. Motheram regarding Lot No. 1344985. (ECF No. 15-23, Kuzmich Dep. 192:23-193:4);
- The fact that she became aware of Lot No. 1344985 after The Medicines Company had paid the issue fee but before issuance of the '727 and '343 patents. (*Id*., Kuzmich Dep. 185:2-186:4);
- The fact that Dr. Motheram believed "there were issues surrounding Ben Venue procedures following manufacturing processes." (*Id*., Kuzmich Dep. 198:23-25);
- The fact that the FDA had warned Ben Venue about manufacturing issues that may constitute violations of the Food Drug and Cosmetic Act. (*Id*., Kuzmich Dep. 197:11-16) (Q. "What manufacturing issues at Ben Venue did [Dr. Motheram] tell you about? A. "He talked about issues related to FDA 483 citations and issues surrounding Ben Venue manufacturing processes and procedures."); and
- The fact that in The Medicines Company's and Dr. Motheram's technical opinion "the [new compounding] procedure was not followed for [Lot No. 1344985], that batch." (*Id*., Kuzmich Dep. 199:3-7).

Dr. Kuzmich testified as to these discoverable facts because "[attorney-client] privilege simply protects the communication from discovery, the underlying information contained in the

communication is not shielded from discovery." *In re Six Grand Jury Witnesses*, 979 F.2d 939, 944 (2d Cir. 1992). "Not all communications to an attorney are privileged." *In re Gaming Lottery Sec. Litig.*, 2000 WL 1171166, at *6. To the extent that the Court finds that a privileged communication existed, the Court should deny Mylan's motion because Dr. Kuzmich only disclosed nonprivileged facts, which the attorney-client privilege does not protect.

C. To the Extent a Waiver Has Occurred, the Court Should Narrowly Construe It to the Subject Matter of Dr. Kuzmich's Conversation with Dr. Motheram

The scope of any waiver must be limited to the subject matter disclosed. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1372 (Fed. Cir. 2007) (restricting scope of waiver of the attorney-client privilege to only those communications related to the subject matter actually disclosed). Mylan improperly seeks communications between Dr. Motheram and the FLH prosecution team regardless of the subject matter of that communication. (Mem. at 11-13.) While FLH does not believe that the conveyance of factual information can give rise to a waiver, to the extent a waiver has occurred, it should be restricted to only those communications related to the specific subject matter disclosed by Dr. Kuzmich, i.e., communications between Drs. Kuzmich and Motheram concerning Lot No. 1344985. *See, e.g., Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1349 (Fed. Cir. 2005) ("The widely applied standard for determining the scope of a waiver . . . is that the waiver applies to all other communications relating to the same subject matter.").

To the extent a waiver occurred—an assertion that FLH disputes—the subject matter should be limited to:

- The details concerning Dr. Kuzmich's conversation with Dr. Motheram regarding Lot No. 1344985;
- Dr. Motheram's belief that Ben Venue experienced manufacturing issues;
- Ben Venue's violations of good manufacturing practices and warnings from the FDA to Ben Venue about manufacturing issues; and

- Ben Venue's failure to follow the new compounding procedure for Lot No. 1344985.

Mylan's attempt to compel "documents and information concerning all of Dr. Motheram's alleged communications with TMC's patent prosecution team" (Mem. at 12) (emphasis added) is inappropriate and well beyond the scope of any waiver—if there was a waiver.

D. Dr. Kuzmich Should Not Be Required to Appear at a Second Deposition Because Mylan Had Full and Fair Opportunity to Question Her During Her First Deposition

Mylan argues, without any authoritative support, that Dr. Kuzmich should be produced for a second deposition because Mylan will question her regarding documents that FLH will produce as a result of its purported waiver. (Mem. at 12.) As an initial matter, counsel for FLH has reviewed the documents listed on FLH's supplemental privileged document log and confirms that there are no documents discussing Lot No. 1344985. (*See* Fleming Decl. ¶¶ 2-5.) The lack of any privileged documents concerning Lot No. 1344985 moots Mylan's request for a second deposition of Dr. Kuzmich.

To the extent Mylan asserts it should be able to take a second deposition of Dr. Kuzmich to ask questions related to FLH's January 11, 2013 production, that request should also be denied. First, the timing of FLH's second supplemental production did not prejudice Mylan because Mylan had all or substantially all of the information in FLH's January 11th production before Dr. Kuzmich's deposition. Specifically, The Medicines Company had previously produced multiple spreadsheets to Mylan that contain the same, or substantially the same, information that Mylan currently seeks in its motion. In fact, Mylan questioned Dr. Kuzmich about one such spreadsheet during her deposition.

Second, Mylan had ample opportunity to question Dr. Kuzmich regarding its inequitable-

conduct defense and has already obtained all of Dr. Kuzmich's understanding concerning Lot No. 1344985. As Dr. Kuzmich confirmed:

> Q. [Dr. Motheram] just said there were some FDA 483 citations and issues surrounding Ben Venue manufacturing processes and procedures and so I don't think the new compounding process was followed and he just left it at that?
>
> . . .
>
> A. [Dr. Motheram's] statement was that there were issues surrounding Ben Venue procedures following manufacturing processes. There had been 483 FDA citations and that the view or the opinion at [T]he Medicines Company and in his view was that the procedure was not followed for [Lot No. 1344985], that batch. That is the information he gave us.
>
> Q. There was no more detail than that?
>
> A. No.
>
> Q. Did he send you any documents related to the investigation regarding that lot?
>
> A. He did not send me any document related to the -- to any investigation.

(ECF No. 15-23, Kuzmich Dep. 198:13-199:16) (emphasis added.) There is no justification for a second deposition of Dr. Kuzmich. Since her deposition, no new material information has been produced that would warrant an further examination.

IV. CONCLUSION

Dr. Motheram provided facts to Dr. Kuzmich and did not provide information for the purpose of obtaining legal advice. As the attorney-client privilege did not attach to Dr. Motheram's oral communication, there could be no waiver. In the alternative, should the Court find that this was a privileged communication and there was a waiver, the waiver should be

limited to the communication between Drs. Kuzmich and Motheram concerning Lot No. 1344985 and Ben Venue's manufacturing issues.

This Court should also deny Mylan's motion to compel production of documents and for a second deposition Dr. Kuzmich. FLH has already collected, produced, and logged documents responsive to Mylan's subpoena. FLH's production includes the "three spreadsheets" that Mylan seeks. Dr. Kuzmich should not be required to appear for a second deposition because Mylan had a full and fair opportunity to question her at her first deposition. Dr. Kuzmich has already testified to the full extent of her knowledge concerning her conversation with Dr. Motheram. Accordingly, FLH respectfully requests that the Court deny Mylan's motion to compel in its entirety.

Dated: January 29, 2013

Respectfully submitted,

/s/ Porter F. Fleming
Porter F. Fleming (PF-1510)
Angus Chen (AC-2995)
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500
PFleming@flhlaw.com
AChen@flhlaw.com

Attorneys for Nonparty Frommer Lawrence & Haug LLP and Plaintiff The Medicines Company

CERTIFICATE OF SERVICE

I, Alyse Mauro, certify that on this 29th day of January 2013 I electronically filed the following document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record:

- *Nonparty Frommer Lawrence & Haug LLP's Memorandum in Opposition to Mylan Inc.'s, Mylan Pharmaceuticals Inc.'s, and Bioniche Pharma USA, LLC's Motion to Compel*

I also served a copy of this document to the following counsel by e-mail:

Scott D. Eads
SEads@perkinscoie.com
Perkins Coie LLP
1120 N.W. Couch Street
Tenth Floor
Portland, OR 97209-4128

James B. Coughlan
JCoughlan@perkinscoie.com
Perkins Coie LLP
131 South Dearborn Street
Suite 1700
Chicago, IL 60603-5559

Autumn N. Nero
ANero@perkinscoie.com
Emily J. Greb
EGreb@perkinscoie.com
David E. Jones
DEJones@perkinscoie.com
Perkins Coie LLP
One East Main Street
Suite 201
Madison, WI 53703

Shannon M. Bloodworth
SBloodworth@perkinscoie.com
Perkins Coie LLP
700 Thirteenth Street, N.W.
Suite 600
Washington, DC 20005-3960

Dennis C. Hopkins
DHopkins@perkinscoie.com
Manny J. Caixeiro
MCaixeiro@perkinscoie.com
Perkins Coie LLP
30 Rockefeller Plaza
25th Floor
New York, NY 10112-0015

/s/ *Alyse Mauro*